IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

CENTRAL FAX CENTER

In re Application of Strobel H. et al.

Examiner:

Powers, Fiona

NOV 2 8 2006

Art Unit:

1626

Application No.: 10/634,979

TELEFAX CERTIFICATE

Filed:

August 5, 2003

I hereby certify that this correspondence is being transmitted via facsimile to the Commissioner for Patents, Alexandria, VA 22313, on

Title:

Acylamino-Substituted Heteroaromatic

Compounds And Their Use As

Pharmaceuticals

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

Dear Sirs:

In response to the Examiner's Advisory Action mailed October 24, 2006, wherein the Examiner maintained the rejection under 35 U.S.C. § 112, first paragraph over claims 1, 6-8, 11 and 12, Applicants respectfully request review of the outstanding rejection. Applicants file concurrently herewith a Notice of Appeal and a Petition for Extension of Time for one month, or until November 30, 2006.

In the final Office Action mailed July 31, 2006 (hereinafter "the Action), the Examiner rejected claims 1, 6-8, 11 and 12 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. Specifically, the Examiner asserts that "[t]he proviso that was added to claim 1 is new matter since the provisoing out of specific compounds that are not specifically disclosed in the specification is new matter. See Ex parte Grasselli, 231 USPQ 393." (See the Action, page 2).

Applicants submit that the Examiner's rejection is improper as claims 1, 6-8 11 and 12 indeed comply with the written description requirement. The first paragraph of 35 U.S.C. § 112 requires an applicant to convey with reasonable clarity to those skilled in the art that, as of the filing date, the applicant was in possession of the claimed invention. In the present application, Applicants' claimed invention is directed to compounds of formula (I) minus one specific species, 2-methyl-6trifluoromethyl-1H-indole-3-carboxylic acid benzothiazol-2-ylamide. Applicants submit that there is ample basis for Applicants claiming such "limited genus". The specification exemplifies a plethora of species that are within this "limited genus". Thus, there is sufficient written description in the

originally-filed specification that conveys with reasonable clarity to those skilled in the art that, as of the filing date, Applicants were in possession of the claimed invention, i.e., the "limited genus".

Furthermore, the Examiner's assertion that the proviso added to claim 1 is new matter contravenes current U.S. case law. With respect to provisos added to claims during prosecution to exclude aspects of the prior art, in <u>In re Johnson and Famham</u>, 194 U.S.P.Q. 187 (CCPA, 1977) (hereinafter, "In re Johnson"), the Court indicated,

Inventions are constantly made which turn out not to be patentable, and applicants frequently discover during the course of prosecution that only a part of what they invented and originally claimed is patentable. It is for the inventor to decide what bounds of protection he will seek. To deny applicants [the benefits of an earlier filing date] would. Let form triumph over substance, substantially eliminating the right of an applicant to retreat to an otherwise patentable species merely because he erroneously thought he was first with the genus when he filed. (In re Johnson, at 195, 196, emphasis added).

The Court went on to rule that,

Here, as we hold on the facts of this case, the 'written description' in the 1963 application supported the claims in the absence of the limitation, and that specification, having described the whole, necessarily described the part remaining...[U]nder these circumstances...appellants are merely excising the invention of another, to which they are not entitled, and are not creating an 'artificial subgenus' or claiming 'new matter.' (Id. at 196, emphasis added).

In addition, in <u>Ex parte Parks</u>, 30 USPQ2d 1234, 1236 (Bd. Pat. App. & Inter. 1993), the Board states that "the observation of a lack of literal support does not, in and of itself, establish a prima facie case for lack of adequate descriptive support under the first paragraph of 35 U.S.C. 112." [See also MPEP § 2173.05(i)].

In the present case, the proviso was added to claim it to exclude one specific compound cited in prior art, i.e., a compound to which Applicants are not entitled. Such proviso does not create an "artificial subgenus" or introduce any "new matter".

Applicants also would like to point out that as In re Johnson and Farnham is a case decided by the Court of Customs and Patent Appeals, its ruling controls over Ex parte Grasselli cited by the Examiner, which was decided by the Patent and Trademark Office Board of Appeals.

In view of the above remarks, the Examiner's rejection is clearly improper and Applicants respectfully request that it be withdrawn. Early notice to this effect is, thus, respectfully requested.

The Commissioner is hereby authorized to charge the fee required and any additional fees that may be needed to Deposit Account No. 18-1982 in the name of Aventis Pharmaceuticals Inc.

Respectfully submitted,

Date: November 28, 2006

Jiang Lin, Reg. No. 51,055 Attorney for Applicants

sanofi-aventis U.S. LLC.
Patent Department
Route #202-206 / P.O. Box 6800
Bridgewater, NJ 08807-0800
Telephone (908) 231-3582
Telefax (908) 231-2626

sanofi-aventis Docket No. DEAV2002-0056 US NP